

# **SPL Process ER/DL Meeting Meeting Minutes Aug 10, 2016**

**Chair of today's meeting:** Pat Cowall

Teleconference information:

USA Toll-Free: 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

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## Agenda:

### 1. SPL topics (Lonnie Smith)

- Basis of strength
- Package level start / end dates in the NSDE file

#### Meeting discussion:

- Basis of strength:
  - When files are being updated to reflect the basis of strength, you need to correct both the flag for the basis of strength....and also to correct the strength information.
  - FDA's system can't check to make sure that you are changing the strength number. Therefore you need to make sure that you check the actual strength.
  - Active ingredient/active moiety spreadsheet: specifies what the basis of strength should be and SPL validation is now checking for this. FDA is noticing that there are files that were updated, but the strength hasn't been updated to correspond to the new basis of strength.
  - Bottom line: check the strength value to make sure it is consistent with the basis of strength.
  - If people have questions, let us know – we can plan a webinar .
- Package level start / end dates in the NSDE file (CMS – Medicare/Medicaid):
  - CMS uses this to determine when the product can be reimbursed. Looking for fraudulent claim activity.
  - These are now being accepted in SPL – for products regulated by CDER. Not CVM or CBER only products. This is OPTIONAL.
  - Reason: In the past, these dates were calculated on when the change was submitted to the SPL files. Companies wanted to specify the actual start/end dates for each pack size based when the package level was introduced / removed

- For products that the product isn't being marketed currently, put in a future market start date – far in the future.
- Take into consideration other potential needs for the SPL – ie getting RxCUI numbers for your products, so that it can be used
- If any of the products has a future market start dates, the SPL file will not be posted on Dailymed – therefore, if you need the file posted on Dailymed, you need to submit the file without the product so that the COL gets posted. Then resubmit the file with the delayed/unmarketed item.
- Pack level market start/end: Use is recommended -- but not required.
- If you submit a market end date BY MISTAKE, and then remove it – there may be an issue with the NSDE file. Check, and contact [SPL@fda.hhs.gov](mailto:SPL@fda.hhs.gov) to get this corrected.

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## 2. Question on new document type: Drug for further processing (Lonnie Smith)

Please clarify the process for implementing the new “Drug For Further Processing” document type and any timing for the implementation of validation check changes.

- how long will we be able to submit a listing with a document type of “bulk ingredient” (53409-9) and a marketing category of “drug for further processing” (C94795)?
- how long will we be allowed to change the document type of a file (setid) from “bulk ingredient” (53409-9) to the new document type of “drug for further processing” (C78744-0)?
- When will these validation rules be implemented?

4.1.1.2 If a document with the same set id has been previously submitted, then it is of the same type, except if the previous document type was Bulk Ingredient (53409-9) and the present document type is Drug for Further Processing (78744-0).

3.2.9.5 If the document type is 53409-9 (bulk ingredient) or Drug for Further Processing (78744-0), then the marketing category is C73626 (bulk ingredient), C94795 (drug for further processing), C96793 (bulk ingredient for human prescription compounding), C98252 (bulk ingredient for animal drug compounding), or C73590 (export only).

### Meeting discussion:

- There is a long history. The doc type of “bulk ingredient” has been used since 2009, with a marketing category of “drug for further processing.” Companies said that this was confusing and wanted a separate doc type.
- This validation procedure was written so that there would be no need for manual overrides.
- How long will we be able to use doc type of “bulk ingredient” with a marketing category of “drug for further processing”? Answer: For quite some time. There are many files with doc type of “bulk ingredient”. At some point they will query the system to see if most companies have made the switched over.

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3. NDC codes for commercial versus samples (Smitha Mathew)

Do companies issue separate NDC codes on carton and container for Commercial and Professional samples/Not for Sale sample –

- We do not print the NDC code on the sample labeling itself.
- For drug listing, you need to establish an NDC for the sample
- There is no NDC code for the inner sample.

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4. Does anyone have an example of a kit (drug cartridge and device injector packaged together in a carton), Smitha Mathew

- if the device injector does not contain drug, do you still assign a NDC code to it?

Meeting discussion:

- Product is currently co-packaged ( drug with a device). But the device is being split out as a separate device.
- Devices that are packaged with a UDI, cannot have an NDC.
- Pfizer: replaced class 3 device which used an “NDC look-alike” with a “GTIN” – uses NDC as a base....and is printed on the label....and can be used for reimbursement.

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5. **Coming Event: SPL Jamboree 2016: Tuesday Sept 27, 2016**

- **Hotel deal: Doubletree Bethesda, by September 2<sup>nd</sup>**
  - o **If you would like a room at the bulk rate, send email to [newtownhogan@comcast.net](mailto:newtownhogan@comcast.net)**
- **Special SPL Team Meeting : Monday, Sept 26, 2016, starting at 6 for dinner and informal discussions.**

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6. SPL REMS update – setting up a discussion group (Pat, Terry , et al.)

- Future discussions will be coming: Do we need a REMS discussion group – with those people that have REMS?
  - o Keith Fisher (Point of Care) – would be willing to help lead these discussions. He will contact Tom Bizarro (First Data Bank) and see if they can work together to help lead this discussion.
  - o Bill Friggle will help provide an industry perspective.
  - o Pat will ask Ed Millikan from ASHP to share his experiences with problems implementing REMS.
  - o We will plan an SPL Process ER/DL meeting following the FDA REMS SPL kickoff – questions resulting from the FDA meeting, and these questions, etc.
  - o If you are interesting in participating, please let us know

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Ongoing followup items:

**Dual FEI numbers – any updates?**

- In 2008, companies were assigned multiple FEI numbers – especially for foreign sites. I.e. a site had 2 FEI numbers, and FDA was requesting changing to the newer number, potentially different from what was in registrations.
- Who should you contact to correct this?

Information from January meeting minutes:

- eDRLS office and then forwarded to the ORA office.
- ORA: Irma Rivera: [irivera@ora.fda.gov](mailto:irivera@ora.fda.gov)
- ORA: Susan Laska: [Susan.Laska@fda.hhs.gov](mailto:Susan.Laska@fda.hhs.gov)
- Any other updates on this?